

NON-TECHNICAL ABSTRACT

In the United States an estimated 25,400 new cases of ovarian cancer will be diagnosed, and approximately 14,500 women are expected to die from their disease in 1998. The p53 gene is frequently altered (either abnormal or absent), in the tumors of women with ovarian cancer. The incidence of p53 gene mutation has been reported in 50-80% of ovarian carcinomas. In experiments using cells in test tubes and in animal models, introducing a normal copy of the p53 gene into cancer cells that have an abnormal p53 gene has been shown to decrease tumor growth.

Current standard treatment for ovarian cancer includes surgery to remove all or as much of the tumor as possible, followed by combination chemotherapy. In patients who receive standard therapy, the 5 year survival rate is 55%.

SCH 58500 is a novel form of treatment called "gene therapy". SCH 58500 uses a virus to deliver the normal gene into a tumor that has lost normal gene function. The modified virus has been constructed from an adenovirus most frequently associated with the common cold. The virus has been modified so that the parts of the virus necessary to reproduce itself have been removed and replaced by the normal p53 gene.

This study is designed to evaluate any additional efficacy of SCH 58500 to standard chemotherapy in women with newly diagnosed ovarian cancer. The resultant virus is not expected to be able to multiply in the patient. All patients in this trial will receive standard chemotherapy. Half of the patients on this trial will receive SCH 58500 in addition to chemotherapy. The treatment will follow standard of care, which includes surgery and standard chemotherapy. This trial will also continue to evaluate the safety of SCH 58500 when combined with chemotherapy.